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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/378-939 01/26/95 CROWE

18M2/0928

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EXAMINER

ADAMS, D

ART UNIT

PAPER NUMBER

28

1806

DATE MAILED:

09/28/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 1/26/95 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> |

Part II SUMMARY OF ACTION

- ☒ Claims 1-14 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
- ☒ Claims 15-31 have been cancelled.
- ☐ Claims _____ are allowed.
- ☒ Claims 1-14 are rejected.
- ☐ Claims _____ are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.
- ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
- ☐ Formal drawings are required in response to this Office action.
- ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
- ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
- ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
- ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
- ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
- ☐ Other

EXAMINER'S ACTION

15. Claims 15-31 have been cancelled.
16. Claims 1-14 are currently pending.
17. Formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84. Applicants' cancellation of Figure 1 is noted and is not deemed to introduce new matter. Applicants' request to hold in abeyance the formal drawing requirements is noted.
18. Claims 1-14 stand rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is not enabling for the use of the claimed invention as a diagnostic aid or as a therapeutic agent. Applicant does not appear to have traversed this grounds of rejection. The specification fails to adequately teach how to use (i.e. provide a written description on how to use) the antibodies made in accordance with the claimed invention as diagnostic aids. A single sentence stating, in passing, that the antibodies rescued in accordance with the claimed invention is not sufficient to enable the use of said antibodies in general diagnostic assays.
19. Claims 1-2, 4-5, 7-10, 12-14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Gillies et al. Gillies et al. teach methods for the production of human (primate) antibodies (specifically anti-tetanus antibodies) from cDNA libraries, as well as transfected cell lines, transfecting vectors, and a recombinant human (primate antibody that would be useful for the treatment of tetanus poisoning (see Materials and Methods). Applicant argues that the specification teaches the cloning and insertion of the entire cDNA sequence encoding the heavy and light chain of immunoglobulin molecules into a vector. No such claim limitation exists. Applicants' arguments appear to cover critical features of the invention that are not claimed. Even if such limitations were present, Applicants' specification indicates that methods of inserting complete cDNA sequences into expression vectors were known before the time of invention of the claimed subject matter (see page 14, paragraph 2). Applicants' claims, if amended to contain the argues limitations would be rejected under 35 USC 103 over Gillies et al. in view of the admitted prior art. For this reason, Applicants' arguments are not found persuasive.
20. Claims 3 and 6 stand rejected under 35 U.S.C. § 103 as being unpatentable over Gillies et al. in view of Fount et al. (WO 87/01131) and Ehrlich et al. Applicant traverses on the grounds that Gillies et al. teach away from the claimed invention in that the insertion of intact cDNA is not

taught. Applicant would appear to be arguing claim limitations not present. Even if such limitations were present, Applicants' specification indicates that methods of inserting complete cDNA sequences into expression vectors were known before the time of invention of the claimed subject matter (see page 14, paragraph 2). Applicants' claims, if amended to contain the argues limitations would be rejected under 35 USC 103 over Gillies et al. in view of the admitted prior art. Applicants' arguments have been considered but are not found persuasive.

21. Claim 11 stands rejected under 35 U.S.C. § 103 as being unpatentable over Gillies et al. in view of Larrick et al. The claim is drawn to a method for the production of recombinant antibodies using micro-preps of RNA. Applicant argues that Gillies et al. requires the use of genomic DNA encoding the heavy chain of Ig molecules. Applicants' arguments appear to be directed to unclaimed elements believed to define over the prior art. Even if such limitations were present, Applicants' specification indicates that methods of inserting complete cDNA sequences into expression vectors were known before the time of invention of the claimed subject matter (see page 14, paragraph 2). Applicants' claims, if amended to contain the argues limitations would be rejected under 35 USC 103 over Gillies et al. in view of the admitted prior art. No such limitations exist in the claims, accordingly applicants' arguments are not found persuasive.
22. No claim allowed.
23. This is a File Wrapper Continuation of applicant's earlier application S.N. 07/952,640. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds or art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See M.P.E.P. § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR

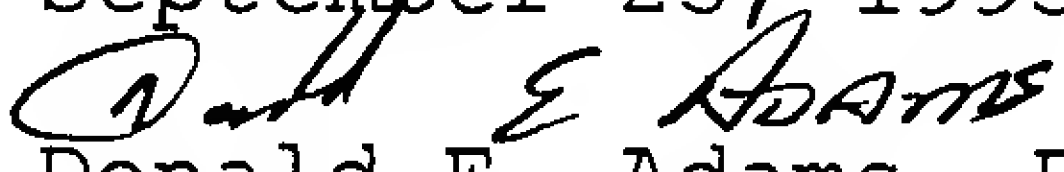
SERIAL NUMBER: 08/378,939
ART UNIT: 1806

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RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS
FINAL ACTION.

24. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4227.
25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donald E. Adams whose telephone number is (703) 308-0570. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Margaret Moskowitz Parr can be reached at (703) 308-2554. The fax phone number for Group 1806 is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

September 25, 1995


Donald E. Adams, Ph.D.
Primary Examiner
Group 1800